BC CANCER
Provincial Health Services Authority

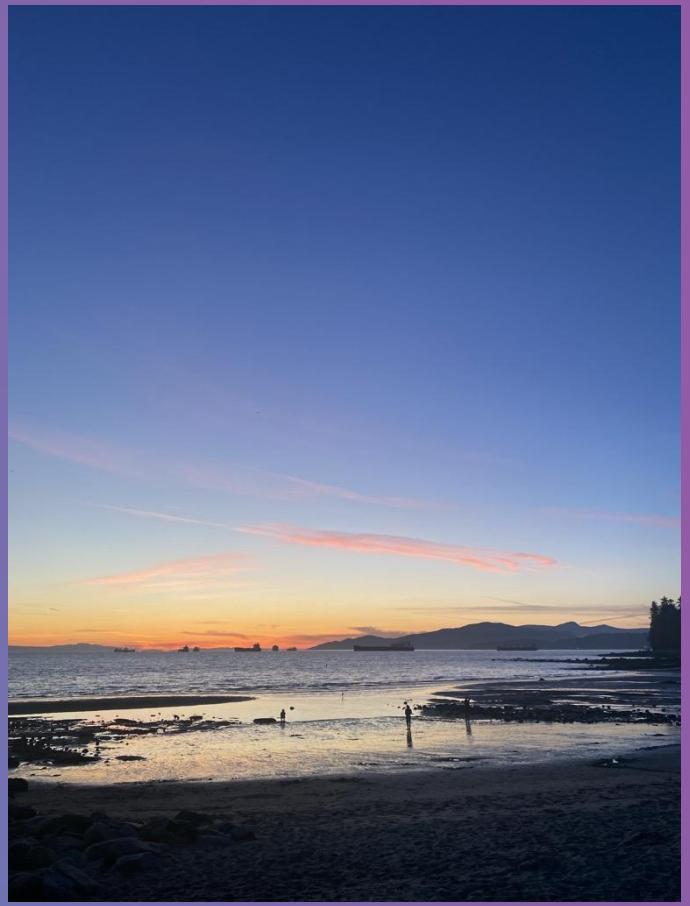
Secondary Use of Data and Chart Review Research

What are ethical considerations, and how can I submit a successful ethics application?

REB Info session - March 21, 2024

Land Acknowledgement

I acknowledge with gratitude, that I am situated on the traditional, ancestral and unceded territories of the ***Coast Salish peoples – xʷməθkʷəy̓əm (Musqueam), sḵwx̱wú7mesh (Squamish), and səlilwətaɬ (Tsleil-Waututh) nations.***



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Who we are

Research Ethics **Board**

- Chair & Vice-Chair
- Community members
- Scientific reviewers
- Ethicists
- Lawyers

Independent body that is **mandated to review** and **maintain** ongoing oversight of the **ethical acceptability of all proposed or ongoing research** involving human participants on behalf of the institution by applying the Tri-Council Core Ethical Principles.

Research Ethics **Office**

- Director
- Officers

Aim to **build capacity** in ethics, **integrity**, and **compliance** through **education, advising, research, policy/guidance development, and administration**. Also responsible for administration relating to the REB.

What we want to achieve today

- Provide clarity on definitions and types of secondary use of data
- When REB review is required vs exempt
- Key ethical concerns - why and how to address them
- Special ethical considerations
- Obtaining consent & Waiver of consent
- RISe application tips & tricks
- Answer your questions

What we won't be focusing on

- Privacy
- Chart review/secondary analyses paired with other research activities
- Multi-site research
- Material incidental findings

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Definitions & Types of Secondary Use

Case: Alex's Project

Alex is conducting a graduate research project and has written up a protocol that involves looking at 15 patients' charts. Alex's supervisor is the medical oncologist who is currently seeing these patients and providing clinical care.

Alex will be accessing patients' charts to collect clinical and demographic information with access to patients' names, PHN and date of birth. Alex will collect more data at a later date that is not yet available in the charts.

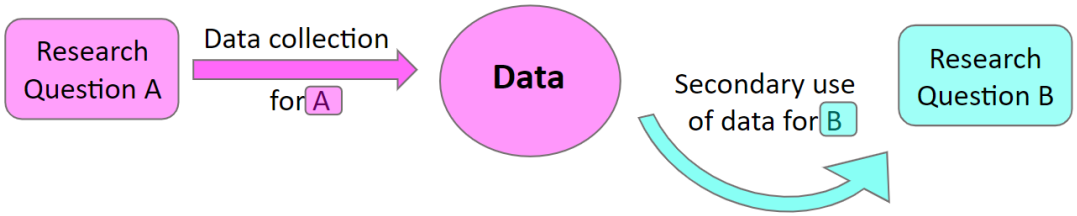
Alex submits this project for REB approval requesting a waiver of consent with a justification that they are working on this project alone with a tight timeline and because this project is minimal risk.

Does Alex's study qualify for Waiver of Consent?

What is Secondary Use of Data?

Secondary use is…

- The use in research of information originally collected for a purpose other than the current research purpose.
  - ➢ Testing new hypotheses that were not described at the time of original data collection



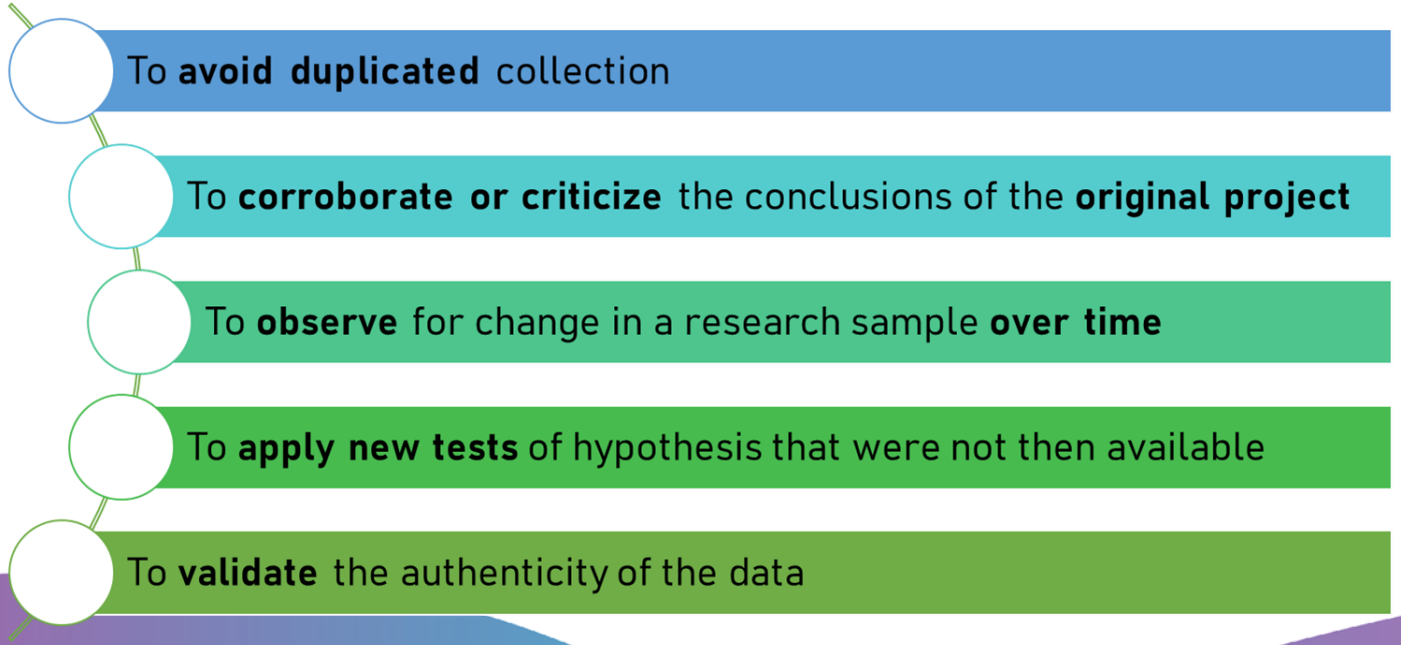
- Types of secondary use research studies differ based on why the data was originally collected.

Common types of secondary use of data in research

Main difference: why the data was originally collected

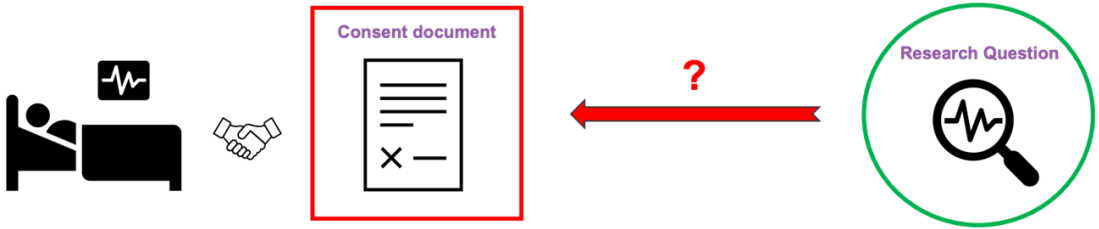
	Chart review	Secondary use of research data	Secondary use of Administrative/Health Data
Original purpose when collected:	**Clinical/treatment**	**Another research** aim and objectives - even within your own lab	**Record keeping** within Government agencies and departments
Examples:	• PHSA's Electrical medical records (EMRs) • Cerner	• Previous/other research studies	• PopData BC • BC Ministry of Health data • Statistics Canada

Why secondary use?



TCPS 2 Chapter 5: https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html#d

Addressing TCPS2 Core Principles: Consent



- How do we ensure ethical principles are maintained in research studies? → Informed Consent Form (ICF)
- Consent defines the bounds of what an individual agrees to for the use of **their data (and samples)**
- Not all data are created equally! **Each dataset has parameters and restrictions** for use according to the **consent document**

Questions about parameters of a specific dataset? → Ask the study PI

Types of Data

HIGH RISK → LOW RISK

Directly Identifying Data

Data with information that identifies a specific individual

Examples:
Name, personal health number, social insurance number

Indirectly Identifying Data

Data that can identify an individual through a combination of indirect identifiers

Examples:
Date of birth, phone number, address

De-identified (Coded) Data

Data with direct identifiers removed and replaced with a unique code. Re-identification is possible

Example:
PI retains a Master Link log that links the coded data with direct identifiers

Anonymized Data

Data are irrevocably stripped of direct identifiers; a code is NOT kept to allow future re-linkage

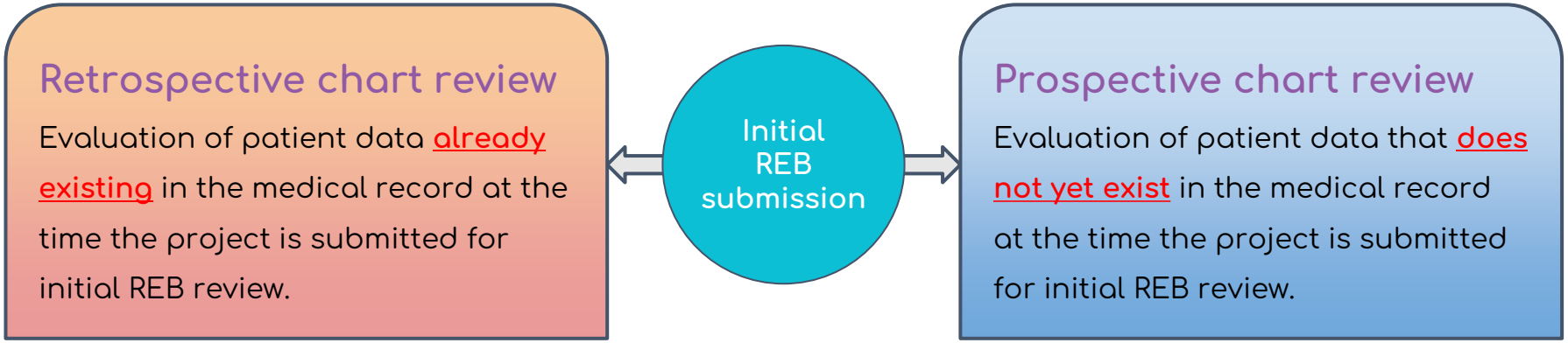
Anonymous Data

Never had identifiers linked to the data

Examples:
Anonymous survey results

TCPS 2 Chapter 5: https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html#a

Chart Review: Retrospective vs Prospective



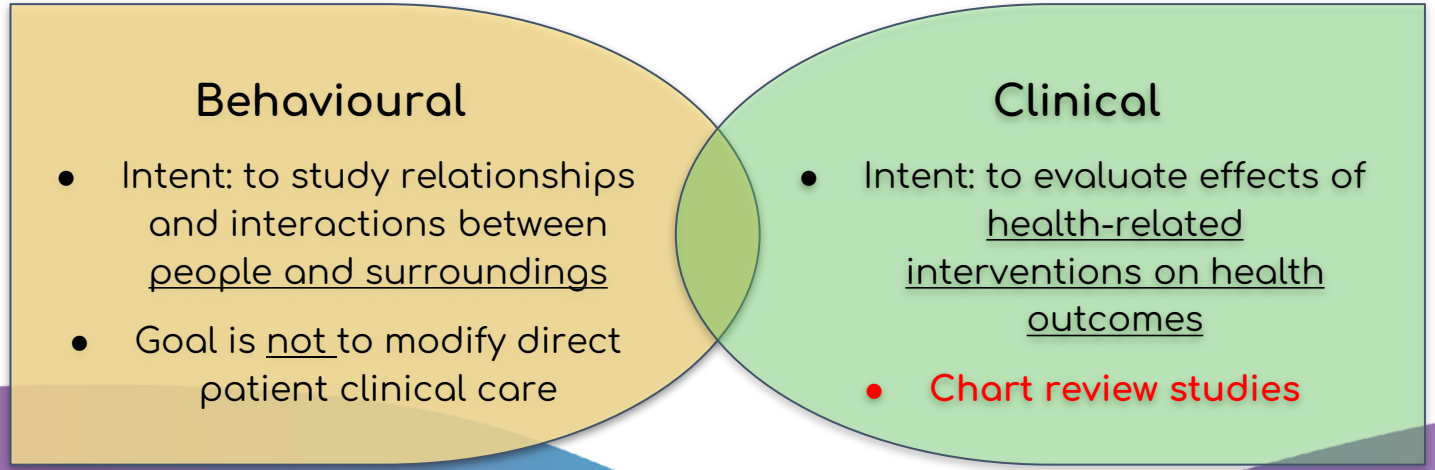
REB Approval should be sought PRIOR to accessing charts/data source

BC Cancer REB Guidance for Chart Reviews:: http://www.bccancer.bc.ca/research-ethics-board-site/Documents/Research%20Ethics%20Board/BC%20Cancer%20REB%20Guidance%20for%20Chart%20Reviews.August%202019.pdf

Behavioural vs Clinical

Difference is often unclear

- Focus on the intent and goal of the project, rather than the method



UBC CREB Guidance Notes: https://ethics.research.ubc.ca/clinical-research-ethics/creb-guidance-notes/part-b-rise-application-guidance-notes

What does REB want to know?

Was consent obtained for use in your specific project?

- How to check?

Clinical Data	Research data	Data from public repositories	Data from public governing bodies
Data obtained from clinical charts	Data collected for research purposes	Data available through data access request E.g. EGA, BC Cancer registry, Popdata BC, CanPath etc.	Data available through legislation or regulation E.g. Ministry of health data, Statistics Canada, etc
Consent for research use has not been obtained. Consider obtaining consent or assess whether your research qualifies for Waiver of Consent.	Consent form of the original study in which the collection was done to check for terms of consent *"Coded data (including genetic information) from this study may be pooled and shared with researchers from around the world for future studies that are unknown at this time."*	Consent should have already be considered by the data custodian, including access and release SOPs.	REB review may not be required.

PHSA Mandate: http://www.phsa.ca/about/who-we-are/our-mandate

Was consent obtained for use in your specific project?

If yes, GREAT! Go ahead with your research project after REB approval has been issued.

If no, obtain consent or assess whether the secondary use in your project qualifies for Waiver of Consent:

a. identifiable information is essential to the research;
b. the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
c. the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information;
d. the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
e. it is impossible or impracticable to seek consent from individuals to whom the information relates;
f. the researchers have obtained any other necessary permission for secondary use of information for research purposes.

TCPS 2 (Chapter 5 - Article 5.5A): https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html#5a

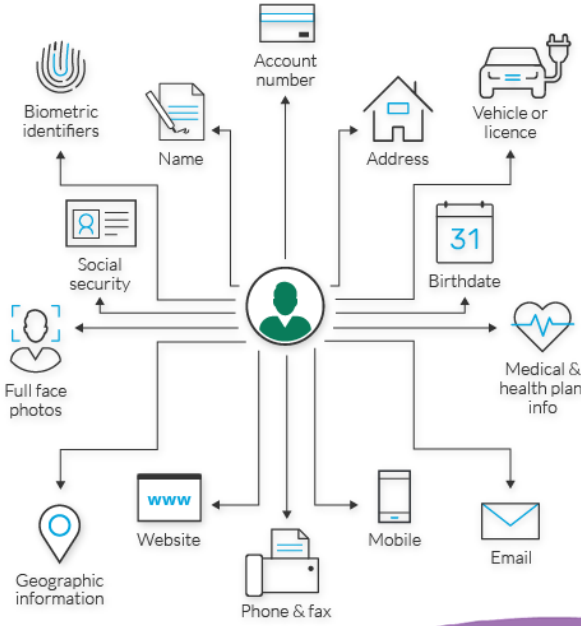
Will you have access to personally identifiable information?

If no, we're less concerned about potential harms.

- Still need REB review

If yes, we need to know more:

- Will they be retained as part of the dataset? Why?
- Will the dataset be anonymized after the final data collection, or will the dataset be de-identified with the personally identifiable information stored separately?
- Was consent obtained?



Considerations on secondary use of genomic data

- Data generated from a research project from unaffiliated labs, collaboratorating labs or *within the same lab* can be extended into new research projects that require new REB applications
- Use of genomic data collected from a clinical study requires an independent REB application *unless* the genomic analysis is described in the initial research application
- Genomic analyses presents unique ethical considerations, such as material incidental findings, potential for patient re-identifiability

Special considerations for data originating from Indigenous Communities

Researchers shall engage the community from which the data or human biological materials and associated identifiable information originate, prior to initiating secondary use where:

1. secondary use has not been addressed in a research agreement and has not been authorized by the participants in their original individual consent; or
2. there is no research agreement; and
3. the data are not publicly available or legally accessible.

References:
TCPS 2 (Article 9.20): https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html#20

REB review is not required when…

Exemptions when research is exclusive relying on:

1) Publicly available information through a mechanism set out by legislation regulation that is protected by law
    - E.g. Statistics Canada, Registries of deaths, Court judgements
2) Information in the public domain (may contain identifiable information) and the individuals to whom the information refers have no reasonable expectation of privacy
    - E.g. public social media content, publications accessible in public libraries, official publications
1) Secondary use of anonymous information as long as identifiable information will not be generated through methods such as data linkage or recording/dissemination of results.

TCPS 2 Chapter 2 - Article 2.2 and 2.4 (Research Exempt from Research Ethics Board Review): https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html

We will question you if...

- Repeated extension of chart dates
- Broader sharing beyond approved project
- Linking data from different sources
- Contacting individuals for additional data under waiver of consent

RISe submission & tips

Clinical
RISe application

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Full Clinical application form

Behavioural
RISe application

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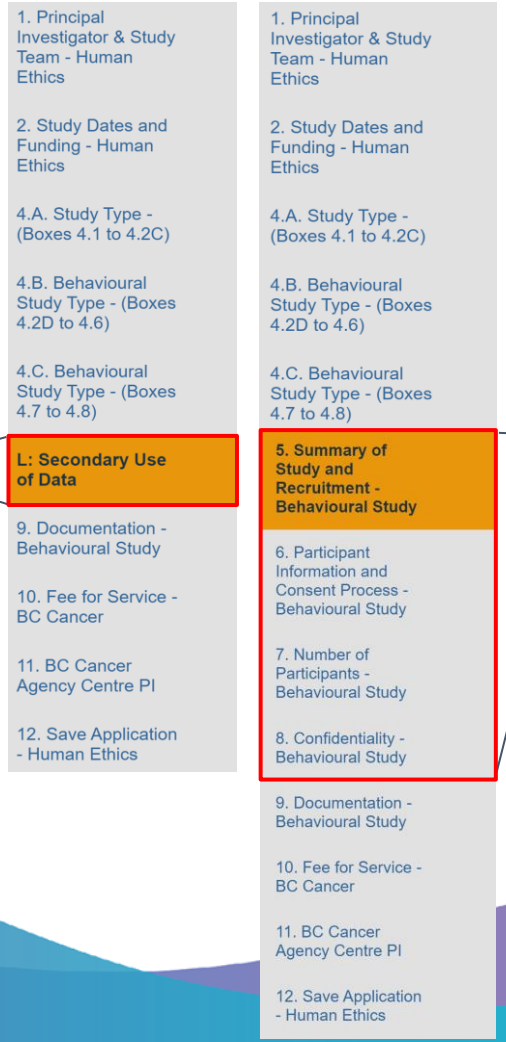
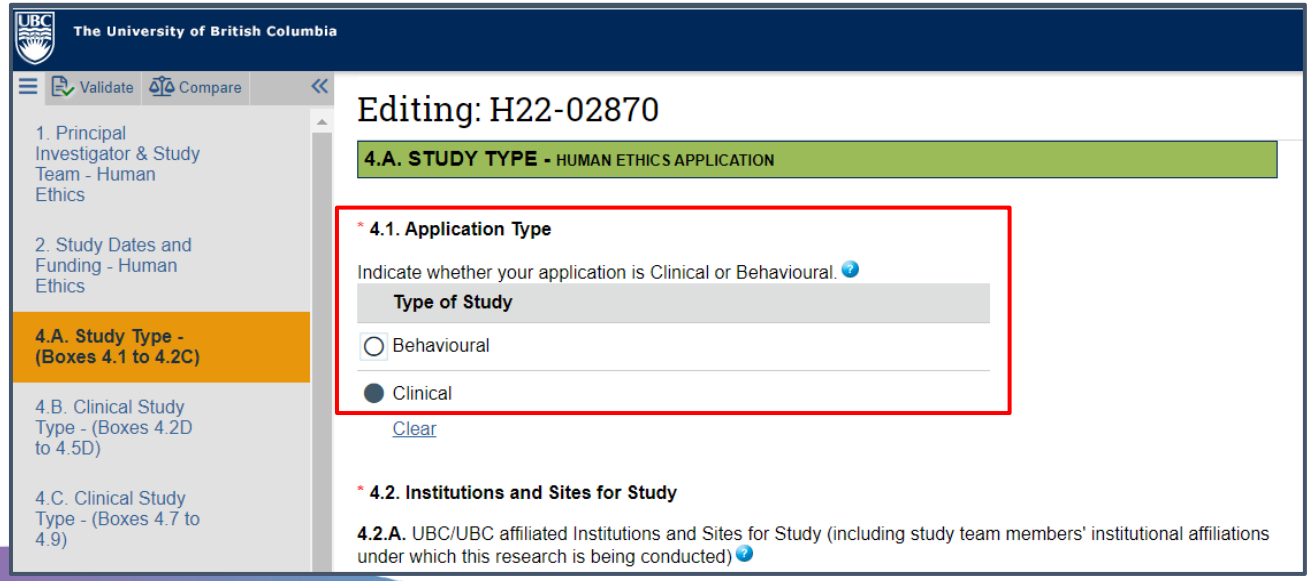
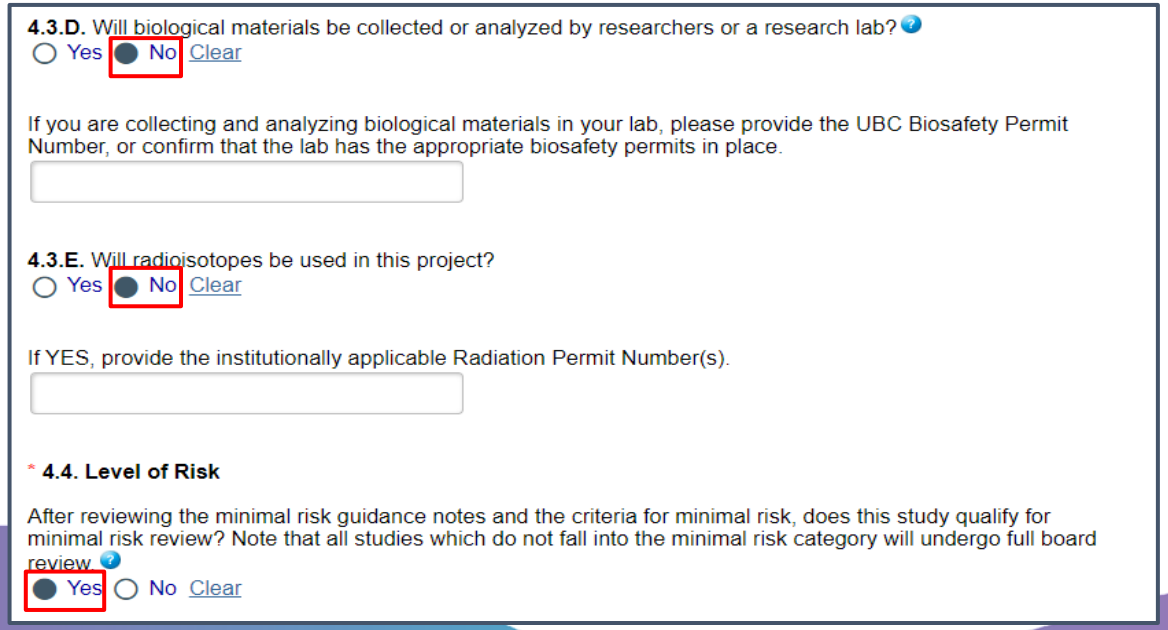


Full Behavioural application form

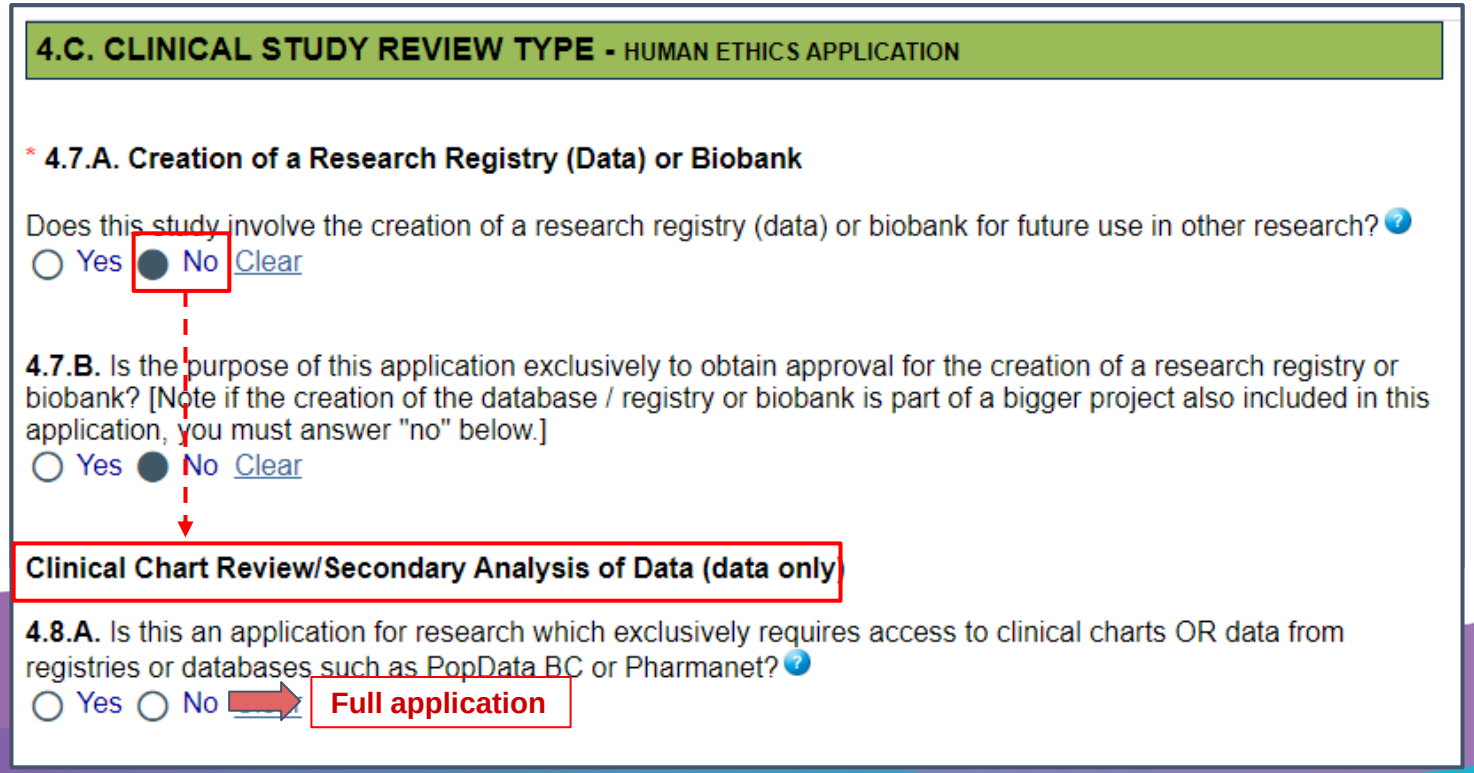
Section 4.A. STUDY TYPE (both clinical and behavioural)



Section 4.B. CLINICAL STUDY REVIEW TYPE



Section 4.C. CLINICAL STUDY REVIEW TYPE



4.C. CLINICAL STUDY REVIEW TYPE - HUMAN ETHICS APPLICATION

* **4.7.A. Creation of a Research Registry (Data) or Biobank**

Does this study involve the creation of a research registry (data) or biobank for future use in other research?

○ Yes ● No Clear

4.7.B. Is the purpose of this application exclusively to obtain approval for the creation of a research registry or biobank? [Note if the creation of the database / registry or biobank is part of a bigger project also included in this application, you must answer "no" below.]

○ Yes ● No Clear

Clinical Chart Review/Secondary Analysis of Data (data only)

4.8.A. Is this an application for research which exclusively requires access to clinical charts OR data from registries or databases such as PopData BC or Pharmanet?

○ Yes ○ No Clear **Full application**

Clinical Chart Review/Secondary Analysis of Data (data only)

4.8.A. Is this an application for research which exclusively requires access to clinical charts OR data from registries or databases such as PopData BC or Pharmanet?

● Yes ○ No Clear

4.8.B. Insert the date range of the charts/data to be included in this research. (e.g. 7 September 2005 – 6 September 2011)

asd

4.8.C. Is this study exclusively a **retrospective** chart/records review where the only source of data will be medical charts/records that are currently in existence? (i.e., will pre-date the date of your initial ethics approval?)

● Yes ○ No → **Full application**

4.8.D. Will you have access to personally identifiable information?

○ Yes ○ No Clear

4.8.E. Is this a retrospective chart review study for which participant consent will be obtained?

○ Yes ○ No → **Page A**

Full application

Section 4.B. BEHAVIOURAL STUDY REVIEW TYPE

Minimal Risk

* **4.5.A.** After considering the level of risk your research involves and the vulnerability of your study population, please tick **one** box below that best represents the overall level of risk.

Participant Vulnerability	Research Risk		
	Low	Medium	High
Low	1 ☑	1 ☐	2 ☐
Medium	1 ☐	2 ☐	3 ☐
High	2 ☐	3 ☐	3 ☐

Please check **one** box only

4.C. BEHAVIOURAL STUDY REVIEW TYPE - HUMAN ETHICS APPLICATION (continue)

* **4.7.A Creation of a Research Database or Registry**

Does this study involve the creation of a research database or registry with a local custodian for future unspecified research?

○ Yes ● No Clear

4.7.B. Is the purpose of this application exclusively to obtain approval for the creation of a research database or registry? [Note: if the creation of the database or registry is part of a bigger project also included in this application, you must answer "no" below].

○ Yes ● No Clear

4.8 * Survey Research

Is this a **minimal risk** study exclusively using a survey for data collection?

○ Yes ● No Clear

4.9 * Secondary Use

Is this a **minimal risk** study exclusively analyzing previously collected data?

● Yes ○ No

Page L

Full application

Take Home Message

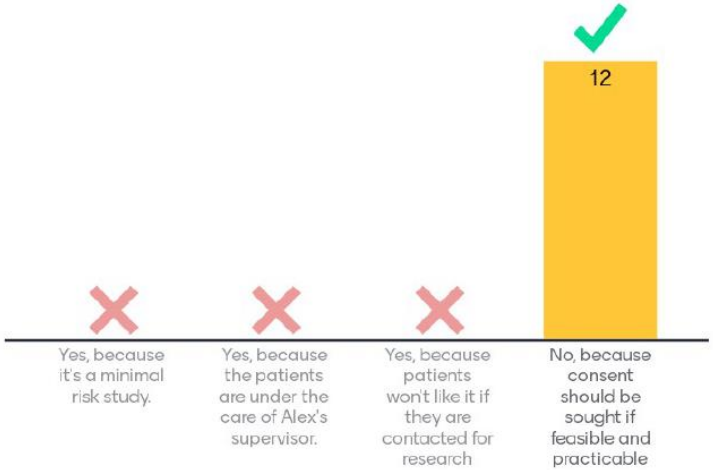
Keep in mind that…

- Projects can be hybrid using mixed methodologies
- When it comes to consent requirements: Benefit vs Risk, feasibility, impracticability assessment
- Use correct terminology to support smooth REB review
- Clear and complete initial REB submission will result in faster approval process
- Reach out to us for consultation: reb@bccancer.bc.ca

Quiz time! 🎉

Alex is conducting a graduate research project and has written up a protocol that involves looking at 15 patients' charts. Alex's supervisor is the medical oncologist who is currently seeing these patients and providing clinical care.
Alex will be accessing patients' charts to collect clinical and demographic information with access to patients' names, PHN and date of birth. Alex will collect more data at a later date that is not yet available in the charts.
Alex submits this project for REB approval requesting a waiver of consent with a justification that they are working on this project alone with a tight timeline and because this project is minimal risk.

Does Alex's study qualify for Waiver of Consent?



What topics you would like to learn about in future sessions? Please be descriptive.

Biosample secondary use

Secondary use of DNA data

third party use of anonymized data

The nature n use of patient-derived materials

How to know when it's a new REB application or a PAA, when using the same secondary data but looking at new things

AI analysis when not specifically consented to initially as it didn't exist when consent signed

When/how do we decide that a research study has expanded enough from an original study such that a new application is needed?

Return of results

What topics you would like to learn about in future sessions? Please be descriptive.

Secondary use of externally collected data (outside of BC Cancer in private clinics) and linking the data to BC Cancer Registry data. Feasibility and REB approval process!

Broad sharing of data where data becomes under the custodianship of external institutions

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Provincial Health Services Authority

Thank you!

Contact us at: REB@bccancer.bc.ca